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# Outcomes of carotid endarterectomy versus stenting in comparable medical risk patients

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***Objective:*** **In medically high-risk patients the choice between carotid artery stenting (CAS) and carotid endarterectomy (CEA) can be difficult. The purpose of this study was to compare risk-stratified outcomes of CAS and CEA.**
***Methods:*** **Patients who underwent isolated primary CEA (n = 11,336) or primary CAS (n = 544) at 29 centers in the Vascular Study Group of New England were analyzed (2003-2013); patients with previous ipsilateral CEA or CAS, or concomitant coronary artery bypass graft were excluded. A medical risk score based on predicted 5-year mortality was developed for each patient using a Cox proportional hazards model. Patients in the highest risk score quartile were termed high-risk (vs normal-risk for the other three quartiles). Medically high-risk patients had a 5-year survival of 65% and comprised 23% of CEA and 25% of CAS patients. Risk-stratified outcomes were compared within neurologically symptomatic and asymptomatic patients.**
***Results:*** **Among asymptomatic patients, rates of in-hospital stroke and/or death were not different between CAS and CEA in normal and high-risk cohorts, ranging from 0.7% in normal-risk CEA patients to 1.6% in high-risk CAS patients. In symptomatic patients, significantly worse outcomes were seen with CAS compared with CEA in normal-risk and high-risk patients. Normal-risk symptomatic patients had a stroke or death rate of 1.3% with CEA, but 5.2% with CAS ($P < .01$). In high-risk symptomatic patients, the stroke or death rate was 1.5% with CEA and 9.3% with CAS ($P < .01$). No significant differences were seen between asymptomatic CEA and CAS within risk strata across secondary outcome measures of stroke, death, or myocardial infarction, and ipsilateral stroke, major stroke, or death. However, symptomatic high-risk CAS patients had significantly greater rates of all secondary outcomes compared with CEA except death, and symptomatic normal-risk CAS patients had only significantly greater rates of death and stroke, death, or myocardial infarction.**
***Conclusions:*** **In the Vascular Study Group of New England, asymptomatic normal- and high-risk patients do equally well after CEA or CAS. However, normal- and high-risk symptomatic patients have substantially worse outcomes with CAS compared with CEA. High medical risk alone might be an insufficient indication for CAS in symptomatic patients. (J Vasc Surg 2014;60:1227-31.)**

In 2005, carotid artery stenting (CAS) received Center for Medicare and Medicaid Services coverage for patients who are at high risk for carotid endarterectomy (CEA) with a symptomatic stenosis >70% (or 50%-70% if participating in a trial), or with an asymptomatic stenosis >80% detected using duplex or angiography if participating in a trial.[1] The Center for Medicare and Medicaid Services defined high-risk in general terms as "having significant comorbidities and/or anatomic risk factors…and would be poor candidates for CEA in the opinion of a surgeon."[1] There has been general agreement that CAS is appropriate in patients with high anatomic risk criteria for CEA, such as previous ipsilateral CEA or other neck surgery, or lesions extending proximal to the clavicle or distal to the C2 vertebral body.[2,3] There has been much greater controversy over medical high-risk criteria,[1,3,4] and it remains unclear which, if any, patients require carotid revascularization but are too medically high-risk for CEA, and in whom CAS is thus preferable.

Comparisons within stratified medical risk groups have been undertaken in select nonrandomized settings. Using the Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy Trial (SAPPHIRE) criteria[3] to define high risk, Mozes et al reviewed their consecutive patient experience with CEA at a single institution and found no statistical difference in major stroke and death rates between their low- or high-risk groups in symptomatic or asymptomatic patients; from this they advocated the treatment option of CEA even in SAPPHIRE-eligible patients at high risk.[5] More recently, within the Society for Vascular Surgery (SVS) Vascular Registry, Schermerhorn et al found after adjusting for symptomatic and high risk status, CAS patients had significantly greater rates of major adverse events than CEA patients with no difference in myocardial infarction (MI).[4]

Randomized controlled trials such as the International Carotid Stenting Study (ICSS) and the Carotid Revascularization Endarterectomy vs Stent Trial (CREST) have shown greater 30-day rates of stroke for CAS relative to

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**Table I.** Demographic characteristics

| | *CEA (n = 11,336)* | *CAS (n = 544)* | P |
|---|---|---|---|
| Hypertension | 88 | 88 | .78 |
| Tobacco use | 79 | 80 | .75 |
| Any CAD | 31 | 43 | <.01 |
| Positive stress test | 10 | 14 | <.01 |
| CHF | 8 | 18 | <.01 |
| Oxygen-dependent COPD | 2 | 5 | <.01 |
| IDDM | 9 | 12 | .01 |
| Renal insufficiency | 6 | 6 | .95 |
| Antiplatelet agent | 91 | 96 | <.01 |
| β-blocker | 75 | 65 | <.01 |
| Statin | 79 | 81 | .36 |

*CAD,* Coronary artery disease; *CAS,* carotid artery stent; *CEA,* carotid endarterectomy; *CHF,* congestive heart failure; *COPD,* chronic obstructive pulmonary disease; *IDDM,* insulin-dependent diabetes mellitus.
Data are presented as percentage.

CEA in symptomatic patients.[6-8] ICSS excluded patients with high-risk anatomic criteria or in whom coronary revascularization was anticipated within a month of the procedure[9] or by investigator determination of risk factors for surgical complications[6] and CREST excluded patients with unstable angina or MI within the past 30 days.[7,8]

The objective of this study was to compare outcomes of CEA and CAS in comparable medical risk patients using the Vascular Study Group of New England (VSGNE) registry to identify opportunities for improving selection for CAS and CEA.

## METHODS

Data were obtained from the VSGNE, a regional cooperative developed in 2002 to improve vascular surgery outcomes; details of the database have been previously published.[10] This database and this study have been approved by the Institutional Review Board at each of the participating institutions. Deidentified CEA and CAS procedures within the VSGNE from January 2003 to June of 2013 were analyzed. Patients who underwent concomitant carotid coronary artery bypass graft or with history of previous ipsilateral carotid revascularization were excluded.

The study sample was comprised of 11,880 patients; 11,336 from 29 centers who underwent CEA, and 544 from 15 centers who underwent CAS. CAS procedures, performed by a mixture of surgeon and nonsurgeon providers, were first recorded in the VSGNE registry in 2005.

The primary study end point was any in-hospital stroke or death. Secondary outcomes included in-hospital stroke, death, or MI, ipsilateral stroke (either major or minor), major stroke (either ipsilateral or contralateral), and death; these were examined according to risk category and procedure.

Baseline patient characteristics are listed in Table I; patients who underwent CAS were slightly younger, more often male, and more often symptomatic. Patients who underwent CAS similarly had a greater prevalence of oxygen-dependent chronic obstructive pulmonary disease and insulin-dependent diabetes mellitus, and a greater burden of cardiovascular disease, assessed as percent with any coronary artery disease, positive stress test, or congestive heart failure (CHF).

**Table II.** Comparison of high-risk designations

| | *Medical high-risk designation* | |
|---|---|---|
| | *Based on VSGNE mortality risk score* | *Based on SAPPHIRE criteria* |
| CEA | 23.4 | 26.6 |
| CAS | 25.3 | 30.8 |

*CAS,* Carotid artery stent; *CEA,* carotid endarterectomy; *SAPPHIRE,* Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy Trial; *VSGNE,* Vascular Study Group of New England.
Data are presented as percentage.

A Cox proportional hazards model was created using backwards stepwise regression to model the risk of 5-year mortality for the cohort as a whole based on medical risk factors. This model included advanced age, preoperative ipsilateral neurologic symptoms, oral medication or insulin-treated diabetes mellitus, any history of tobacco use, oxygen-dependent chronic obstructive pulmonary disease, CHF, coronary artery disease, or end-stage renal disease (dialysis dependence or history of kidney transplantation), lack of a statin, and lack of antiplatelet agent.[11] Risk scores were calculated for each patient using normalized β coefficients from the model,[12,13] and grouped into risk quartiles, with higher scores having greater risk of long-term mortality (Supplementary Fig, online only). The 5-year mortalities of the lower three quartiles of risk score were similar and subsequently classified as "normal risk," for comparisons with the highest risk quartile. The distribution of CEA and CAS within the highest risk quartile was similar in proportion (23% of CEA and 25% of CAS); other demographic characteristics of the normal- and high-risk groups are detailed in the Supplementary Table (online only). We used 5-year mortality estimates as the indicator of overall medical risk in this study.

To validate our calculated medical risk score, we compared the proportion of our sample that would be termed high-risk based on our mortality risk score with the proportion having one or more of the medical high-risk criteria from the SAPPHIRE registry (Table II). Medical components of a SAPPHIRE high-risk designation included CHF, open-heart surgery within 6 weeks, recent MI, unstable angina, abnormal stress test, coexistent severe cardiac and carotid disease requiring open heart surgery and carotid revascularization, severe pulmonary disease, and age ≥80 years.[14,15] Similar proportions of patients were identified as high-risk using the SAPPHIRE medical criteria and our mortality-based score. Additionally, the 5-year survival for patients identified as high-risk using the SAPPHIRE medical criteria did not significantly differ from that of our high-risk cohort.

## RESULTS

Our retrospective analysis of the VSGNE registry examined 11,880 patients who received isolated CEA or CAS, of whom 3960 (33.3%) were symptomatic patients. Among the 7920 asymptomatic patients, 18.5% who received CEA and

**Table III.** Risk stratified periprocedural outcomes among asymptomatic patients

| | *Asymptomatic normal-risk* | | | *Asymptomatic high-risk* | | |
|---|---|---|---|---|---|---|
| | *CEA (n = 6272)* | *CAS (n = 273)* | P | *CEA (n = 1313)* | *CAS (n = 62)* | P |
| Stroke or death | 0.7 | 1.1 | .49 | 1.2 | 1.6 | .78 |
| Stroke, death, or MI | 1.5 | 1.1 | .57 | 2.6 | 1.6 | .63 |
| Any ipsilateral stroke (major or minor) | 0.5 | 1.1 | .16 | 0.8 | 1.6 | .52 |
| Any major stroke (ipsilateral or contralateral) | 0.4 | 0.0 | .33 | 0.3 | 0.0 | .66 |
| Death | 0.1 | 0.0 | .61 | 0.4 | 0.0 | .63 |

*CAS,* Carotid artery stent; *CEA,* carotid endarterectomy; *MI,* myocardial infarction.
Data are presented as percentage, except where otherwise noted.

17.3% who received CAS were considered high-risk. Among the symptomatic patients, 35.7% who received CEA and 35.9% who received CAS were considered high-risk. In asymptomatic patients, no significant difference was seen in stroke or death rates between those who underwent CEA and CAS among normal-risk patients (0.7% with CEA, 1.1% with CAS; $P = .49$) or high-risk patients (1.2% with CEA, 1.6% with CAS; $P = .78$; Table III). These results were consistent with those seen in asymptomatic patients in the CREST trial, in which there was a 1.4% stroke or death rate in asymptomatic CEA and 2.5% in asymptomatic CAS patients ($P = .15$).[7,8,16] No statistically significant differences were noted between CEA and CAS across any of the secondary outcomes, including stroke death or MI, ipsilateral stroke, major stroke, or death.

Among symptomatic patients, significantly worse outcomes were seen with CAS compared with CEA in normal-risk and high-risk patients (Fig).[7,8,16] Normal-risk symptomatic patients had a stroke or death rate of 1.3% with CEA, but 5.2% with CAS ($P < .01$). In high-risk symptomatic patients, the stroke or death rate was 1.5% with CEA and 9.3% with CAS ($P < .01$), and the stroke or death rate was 3.2% for CEA and 6.0% for CAS ($P < .05$) in symptomatic CREST patients.[7,8,16] Similar trends were seen with the addition of MI to the combined end point, with significantly worse outcomes in the CAS group compared with the CEA group, seen in the normal-risk cohort (2.2% CEA vs 6.0% CAS) and high-risk cohort (2.5% CEA vs 9.3% CAS). The stroke rate for each procedure did not significantly differ in symptomatic normal-risk patients, although it approached significance for any ipsilateral stroke at 1.1% with CEA vs 3.0% with CAS; $P = .06$. However, among symptomatic high-risk patients, the rates were significantly greater for CAS for ipsilateral stroke (0.8% with CEA vs 6.7% with CAS) and any major stroke (0.6% with CEA vs 6.7% with CAS; Table IV). Most of the events that contributed to stroke, death, or MI were major strokes in symptomatic high-risk patients treated with CAS.

## DISCUSSION

Comparing CEA and CAS results in real-world practice has often been plagued by the question of whether one group of patients bears a greater disease or comorbidity burden. Although it is commonly accepted that high-risk anatomic factors make CAS a preferred treatment option compared with CEA, the choice between CAS and CEA for carotid revascularization in medical high-risk patients is less clear. By stratifying patients according to symptomatic status and medical risk status, our analysis allows for comparisons between procedures within groups at similar risk of mortality.

Previous work has been done to stratify medical risk of patients who undergo vascular procedures[11,12]; this is important in making treatment selections. Wallaert et al found among asymptomatic high-risk patients in the VSGNE, 5-year survival after CEA was only 51%, and that 20% of asymptomatic patients who underwent CEA had poor predicted long-term survival.[11] These patients fared worse, even in the postoperative period, experiencing significantly greater rates of postoperative stroke and death than their normal medical risk counterparts.[11] This suggests the need to avoid any intervention in high-risk asymptomatic patients not anticipated to live long enough to receive benefits from a prophylactic procedure. Mozes et al, in a single-center consecutive CEA patient experience of symptomatic and asymptomatic patients, found no statistical difference in major stroke and death rates between low- and high-risk patients (based on SAPPHIRE criteria), although the combined stroke death or MI rate was significantly lower in low-risk symptomatic patients.[5] A retrospective study by Gasparis et al, who examined consecutive isolated CEAs at two hospitals with a smaller proportion identified as high risk, came to similar conclusions.[17] These studies have raised the question of whether, based on anticipated procedural outcomes, patients exist who are too high risk for CEA but appropriate for CAS.[5,17]

Review of the VSGNE registry participants suggest significantly worse outcomes in periprocedural stroke, and combined outcomes of stroke or death, and stroke death or MI in symptomatic patients receiving CAS, particularly among medically high-risk patients. Our societal guidelines suggest CAS as an alternative to CEA for symptomatic patients at average or low risk of complications associated with endovascular intervention, with internal carotid stenosis >70% determined using noninvasive imaging or >50% using angiography with an anticipated rate of periprocedural stroke or mortality <6%.[2,18] Within our cohort, the 9.3% periprocedural stroke or death rate in symptomatic high-risk patients failed to meet this threshold.

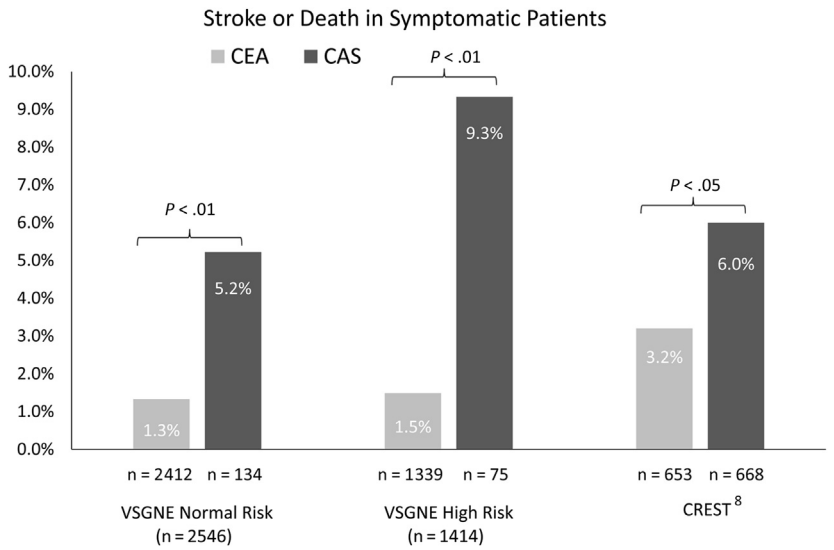


**Fig.** Stroke or death in symptomatic patients compared with Carotid Revascularization Endarterectomy vs Stenting Trial (*CREST*) findings.[8] *CAS,* Carotid artery stenting; *CEA,* carotid endarterectomy; *VSGNE,* Vascular Study Group of New England.

**Table IV.** Risk stratified periprocedural outcomes among symptomatic patients

| | *Symptomatic normal-risk* | | | *Symptomatic high-risk* | | |
|---|---|---|---|---|---|---|
| | *CEA (n = 2412)* | *CAS (n = 134)* | P | *CEA (n = 1339)* | *CAS (n = 75)* | P |
| Stroke, death, or MI | 2.2 | 6.0 | <.01 | 2.5 | 9.3 | <.01 |
| Any ipsilateral stroke (major or minor) | 1.1 | 3.0 | .06 | 0.8 | 6.7 | <.01 |
| Any major stroke (ipsilateral or contralateral) | 0.5 | 1.5 | .10 | 0.6 | 6.7 | <.01 |
| Death | 0.2 | 2.2 | <.01 | 0.5 | 1.3 | .36 |

*CAS,* Carotid artery stent; *CEA,* carotid endarterectomy; *MI,* myocardial infarction.
Data are presented as percentage, except where otherwise noted.

Similar findings were encountered by Giles et al among symptomatic high-risk patients within a 2004 to 2007 national inpatient sample cohort in which symptomatic high-risk CAS patients had a 14.4% periprocedural stroke or death rate.[19]

Our study has several limitations including relatively low event rates, potential selection bias, and possible confounding related to operator volume or changes in outcomes over time. Although we demonstrated a significantly greater stroke or death rate in symptomatic high-risk patients who received CAS compared with CEA, the underlying rates might be even greater. The VSGNE has the potential to underestimate events because only clinically evident stroke and MI are tracked and periprocedural outcomes in VSGNE extend only within the index hospitalization. It is estimated that approximately a third of strokes and cardiac events occur after hospital discharge in symptomatic and asymptomatic patients.[20] However, we would expect the trend of worse outcomes with CAS compared with CEA in symptomatic patients to persist, as the Endarterectomy versus Angioplasty in Patients with Symptomatic Severe Carotid Stenosis (EVA-3S) investigators noted a significantly greater proportion of strokes occurred on the day of the procedure in patients who received CAS rather than CEA.[21] Similarly, Sidaway et al, in examining predischarge vs 30-day outcomes of CEA and CAS, found that an additional 1.79% combined stroke death or MI events take place after hospital discharge from CAS, but only an additional 0.58% occur after CEA.[22]

Other possibilities for discrepancies in event rates between our registry findings and previous trial results include patient and provider selection. Providers within CREST were selected for having previous complication and death rates of less than 3% among asymptomatic patients and less than 5% among symptomatic patients.[7] The highly controlled patient and provider environment of the trials would therefore be expected to yield lower adverse outcome rates compared with routine clinical practice. However, because of the similarity of CEA adverse event rates seen in registry and trial data, the significantly greater adverse event rates observed among CAS patients remains a concern.

Additionally, although our data span a decade timeframe, no systemic early-adopter or provider volume bias was evident, with event rates stable across time within

CEA and only a single year in which there were notably higher CAS event rates (which corresponded with a greater total number of procedures performed that year). No trends were noted among stroke or death rates and methods of embolic protection in CAS, although a comparison across types of embolic protection was underpowered because of the relatively small number of CAS procedures. Additionally, reanalyzing the data excluding the years 2003 and 2004, in which no CAS procedures were recorded, did not affect our findings.

## CONCLUSIONS

Although symptomatic medical high-risk patients are a group in whom CAS is a potentially alluring treatment option, knowledge of local rates of periprocedural adverse outcomes should factor into physician treatment decisions. CAS might be inappropriate for symptomatic high medical risk patients without anatomic indications. In the VSGNE, CEA is the more appropriate intervention for these patients. These results highlight the importance of quality improvement registries in tracking real-world results which might differ from those of randomized controlled trials.

## AUTHOR CONTRIBUTIONS

Conception and design: BN
Analysis and interpretation: ES, PG, AS, DS, MS, RP, JC, BN
Data collection: Not applicable
Writing the article: ES, JC, BN
Critical revision of the article: ES, PG, AS, DS, MS, RP, JC, BN
Final approval of the article: ES, PG, AS, DS, MS, RP, JC, BN
Statistical analysis: ES, BN
Obtained funding: Not applicable
Overall responsibility: ES

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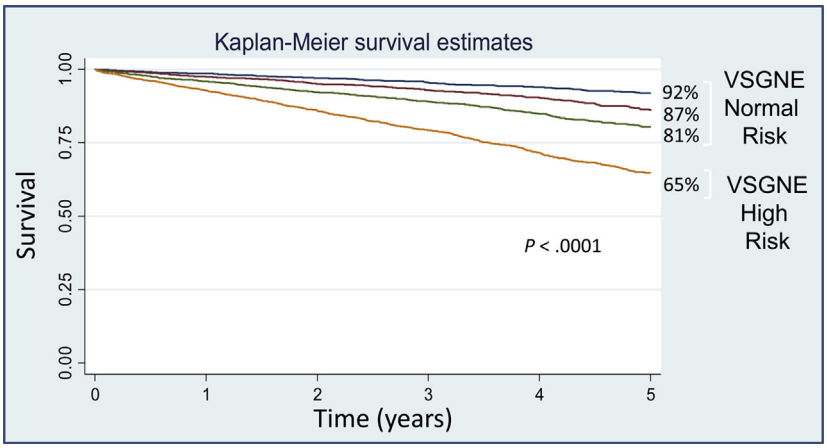


**Supplementary Fig (online only).** Risk-stratified quartiles of survival defining normal- and high-risk cohorts. *VSGNE,* Vascular Study Group of New England.

**Supplementary Table (online only).** Distribution of demographic characteristics according to risk group

| | *Normal-risk (n = 9091)* | *High-risk (n = 2795)* | P |
|---|---|---|---|
| Mean age (standard deviation) | 68 (9) | 76 (8) | <.01 |
| Hypertension | 87 | 91 | <.01 |
| Tobacco use | 78 | 84 | <.01 |
| Any CAD | 25 | 55 | <.01 |
| Positive stress test | 9 | 14 | <.01 |
| CHF | 3 | 24 | <.01 |
| Oxygen-dependent COPD | 0.3 | 6 | <.01 |
| IDDM | 7 | 18 | <.01 |
| Renal insufficiency | 2 | 18 | <.01 |
| Antiplatelet agent | 95 | 79 | <.01 |
| β-blocker | 73 | 78 | <.01 |
| Statin | 86 | 56 | <.01 |

*CAD,* Coronary artery disease; *CHF,* congestive heart failure; *COPD,* chronic obstructive pulmonary disease; *IDDM,* insulin-dependent diabetes mellitus.

Data are presented as percentage, except where otherwise noted.